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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/212,556	12/16/1998	SHINICHI KURAKATA	980689/HG	8315
1933	7590	02/12/2004	EXAMINER	
FRISHAUF, HOLTZ, GOODMAN & CHICK, PC 767 THIRD AVENUE 25TH FLOOR NEW YORK, NY 10017-2023			OWENS JR, HOWARD V	
			ART UNIT	PAPER NUMBER
			1623	

DATE MAILED: 02/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/212,556

Applicant(s)

KURAKATA ET AL.

Examiner

Howard V Owens

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 November 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 69-77 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 69-77 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>11/5/2003</u> . | 6) <input type="checkbox"/> Other: _____ |

Response to Arguments

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/5/2003 has been entered.

An action on the merits of claims 69 - 77 is contained herein below.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

35 U.S.C. 103

Applicant's arguments filed 11-5-2003 have been fully considered but they are not persuasive. The rejection of claims 69-77 rejected under 35 U.S.C. 103(a) as being unpatentable over Kimura et al., EP 0799823 A1 and Ruff et al., Journal of Clinical Investigat., vol. 73, pp. 1483-1486 is maintained for the reasons of record.

Kimura et al., teach the analogous diphenylpyrrole compounds of species 1 of the instant invention. Kimura et al. teach that these compounds as cyclooxygenase-2 inhibitors inhibit prostaglandins. Kimura et al. however does not teach the usefulness of these compounds to treat cachexia or disorders resulting from tumors.

Ruff et al. teach that the inhibition of prostaglandin production counters cachexia or muscle wasting , which adequately bridges the nexus between the differences in the prior art and the invention as claimed.

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It would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made to use the diphenylpyrrole compounds of the instant invention to treat cachexia or side effects of tumor related disorders.

A person of ordinary skill in the art would have been motivated to use these art recognized prostaglandin inhibiting diphenylpyrrole compounds to treat cachexia or side effects of tumor related disorders because the prior art has established the usefulness of prostaglandin inhibitors in countering the muscle wasting or cachexia.

Applicant argues that the examiner has not demonstrated a prima facie case of obviousness because Ruff demonstrated that acetaminophen, a prostaglandin inhibitor (PGI) as deemed by the state of the art at the time of filing, did not prevent muscle wasting. However, assuming *arguendo* that the state of the art recognized that acetaminophen was a PGI that did not prevent muscle wasting. This lone fact does not destroy the teachings of Ruff with regards to the usefulness of PG inhibitors for the treatment of muscle wasting; one of skill in the art presented with the state of the art and Ruff's teachings would simply know that acetaminophen as a prostaglandin inhibitor would not have a likelihood of success in the treatment of cachexia. The standard for obviousness is a reasonable expectation of success, not a guarantee. Thus even if one of skill in the art is presented with an exception, this does not wholly invalidate the suggestion provided by the prior art. The fact that acetaminophen may not work against cachexia, does not remove the suggestion provided to one of skill in the art to have a reasonable expectation in the use of a prostaglandin inhibitor. As cited above, Kimura et al., teach the analogous diphenylpyrrole compounds of species 1 of the instant invention. Kimura et al. teach that these compounds as cyclooxygenase-2 inhibitors inhibit prostaglandins. Ruff provided the nexus for the use of the compounds to treat cachexia as Ruff teaches that the inhibition of prostaglandin production can counter cachexia or muscle wasting.

Applicant states that it was known before and after Ruff that Acetaminophen is a PG inhibitor. However, the Mayo Clinic (11/2002, noted but not relied upon for the rejection of record) has reported that acetaminophen doesn't affect prostaglandins:

"Acetaminophen (Tylenol, others) is most effective for mild to moderate pain that isn't accompanied by inflammation. Unlike COX-2 inhibitors and other nonsteroidal anti-inflammatory drugs (NSAIDs), acetaminophen doesn't affect prostaglandins — a hormone-like substance involved in the development of pain and inflammation. Therefore, it does little to reduce inflammation".

whereas COX 2 inhibitors such as the compounds of the invention (as taught by Kimura) do affect prostaglandins which is consistent with the teachings of Ruff. For the reasons cited above, the examiner maintains the position that there is sufficient motivation in the prior art to use the diphenylpyrrole compounds in the treatment of cachexia.

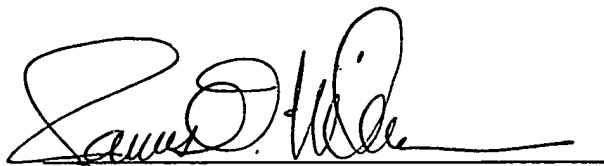
All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Howard V. Owens
Patent Examiner
Art Unit 1623



James O. Wilson
Supervisory Patent Examiner
Technology Center 1600

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Howard Owens whose telephone number is (571) 272-0658 . The examiner can normally be reached on Mon.-Fri. from 8:30 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the Supervisory Patent Examiner signing this action, James O. Wilson can be reached on (571) 272 - 0661.